SEP - 9 2004

510(k) Summary
Carl Zeiss Meditec AG
VISULAS YAG III™

K 042139

This 510(k) summary for the VISULAS YAG III is submitted in accordance with the requirements of SMDA 1990 and 21 C.F.R § 807.92.

GENERAL INFORMATION

Manufacturer:
Carl Zeiss Meditec AG
Carl-Zeiss-Promenade 10
07740 Jena
Germany
Est. Reg. No. 9615030

Contact Person:
Michael Giebe
Manager – Regulatory Affairs

U.S. Agent:
R. Michael Crompton
Vice President, Regulatory/Clinical Affairs
& Quality Assurance
5160 Hacienda Drive
Dublin, California 94568
(925) 557-4353 (phone)
(925) 557-4481 (fax)

DEVICE DESCRIPTION

Classification: Class II

Trade Name: VISULAS YAG III™

Generic/Common Name: Laser Instrument, Surgical, Powered (21 CFR § 878.4810)

PREDICATE DEVICE

(1) VISULAS YAG II*plus*™

INTENDED USE

This device will be used in ophthalmic applications, including posterior capsulotomy and peripheral iridotomy. This device is intended for use primarily by physicians and health care workers and may only be used under the supervision of a physician. This device will not be sold to the general public.

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DEVICE DESCRIPTION

The VISULAS YAG III™is a Neodymium : Yttrium : Garnet (Nd:YAG) laser for ophthalmic applications, including posterior capsulotomy and peripheral iridotomy. The device operates at a wavelength of 1064 nm. The beam diameter is 10μm with a pulse length of <4 ns. The maximum energy output per pulse is 10 mJ.

SUBSTANTIAL EQUIVALENCE

The VISULAS YAG III™ is substantially equivalent to the predicate device identified previously. The VISULAS YAG III™ is substantially equivalent to the predicate device with regard to intended use, operating principle, function, and materials.

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the VISULAS YAG III™ to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Carl Zeiss Meditec AG
c/o Mr. R. Michael Crompton
Vice President, Regulatory/Clinical Affairs
and Quality Assurance
Carl Zeiss Meditec, Incorporated
5160 Hacienda Drive
Dublin, California 94568-7562

Re: K042139
Trade/Device Name: YAG III™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 4, 2004
Received: August 10, 2004

Dear Mr. Crompton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K042139

Device Name: YAG III™

Indications for Use: This device will be used in ophthalmic applications, including posterior capsulotomy and peripheral iridotomy. This device is intended for use primarily by physicians and health care workers and may only be used under the supervision of a physician. This device will not be sold to the general public.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 C.F.R. § 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042137